Drug Utilization Review Board Meeting Minutes, Open Session, July 10, 2019		
Drug Utilization Review Board Meeting Location: DXC Technology, Building #283, Capital Room 6511 SE Forbes Ave, Topeka, KS 66619	**DUR Board Members:** Moneeshindra Mittal, MD (Chair) James Backes, PharmD Jennifer Clair, MD Katie Burenheide Foster, PharmD, MS, BCPS, FCCM LaTonyua Rice, PharmD, CGP Serena Stutzman, APRN Arthur Snow, MD Roger Unruh, DO (Absent) **KDHE/DHCF/Contractor Staff:** Annette Grant, RPh. Victor Nguyen, PharmD Margaret O'Donnell, Transcriptionist **DXC Technology Staff/KEPRO Staff** Karen Kluczykowski, RPh (Absent) Kathy Kaesewurm, RN, BSN Ariane Casey, PharmD **MCO Staff:** Jeanne Cavanaugh, PharmD, UnitedHealthcare Community Plan Alan Carter, PharmD, Aetna Better Health of Kansas Angie Zhou, PharmD, Sunflower State Health Plan	**Public Attendees**: Rob Hanson, Phil King Jim Baumann, Pfizer; Donna Osterland, Kevin Duhrlops, Sanofi Genzyme; Tony Salicos, Shannon Meyer, Greenwich; Erin Hohman, Janssen; Rick Kegler, Krystal Joy, Otsuka; Evie Knisely, Novartis; Marla Wiedeman, NNI; Brenda Kuder, Amy Campbell, KMHC; Meghan Kerrigan, Merck; Susan Zalenski, Dawn Lease, J&J; Rob Kilo, Biran Patel, Biogen; Laura Hill, Melissa Basil; AbbVie, Brian Howell; Avexis *Illegible names on the sign-in sheet were not included.

TOPIC	DISCUSSION	DECISION
I. Call to Order	Dr. Mittal called the meeting to order at 10:06 a.m. (Quorum met)	
Announcements and Introductions	Ms. Grant introduced the new Board member, Arthur Snow, M.D. Ms. Grant announced a change to the Blanket Statement agenda item, adding "The Provider Group identifier would change to Billing Code Type," and also reported that the most recently posted PA Criteria has been edited due to public/provider feedback and follow-up research by the State. Additionally, as requested at the previous April DUR Board meeting, the Hemlibra® draft PA was to be brought back to the July DUR Board meeting. However, the State is not ready to address Hemlibra® at this time.	
II. Old Business **A. Review and Approval of April 10, 2019 Meeting Minutes**	**Board Discussion:** The April 10, 2019 Meeting Minutes will be amended to show Ms. Stutzman listed as absent.	Dr. Backes moved to approve the minutes as amended. Dr. Foster seconded the motion. The motion was approved unanimously.
III. New Business **A. New Preferred Drug List (PDL) Class** 1. Immunomodulation Agents - Asthma	**Background:** At the June 2019 PDL meeting, the committee approved the addition of asthma immunomodulators to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents. **Public Comment:** None. **Board Discussion**: A Board member asked if they need to start with one agent before they move to another or are all they all approved. The State answered that if this PDL class addition is approved, the State will then determine preferred and non-preferred PDL status for these drugs.	Ms. Stutzman moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION
B. Revised Prior Authorization (PA) Criteria 1. Non-Preferred PDL PA Criteria	**Background:** The Non-preferred PDL PA criteria were last updated in April 2019. This is being revised to provide continuity between the PDL program and the Clinical PA program and streamline the PA reviewer process. **Public Comment:** None. **Board Discussion:** The State shared the purpose of tying these documents together is for both clinical programs to be communicating with each other and making sure everything is met on the first request for the drug. The Board asked the MCOs if this step will lead to more or less operational challenges. MCOs replied that it will make it easier because oftentimes a drug can be non-preferred on the PDL, therefore, having to go through the non-preferred PA criteria and they may also have a clinical PA criteria and so there are actually two criteria you would have to go through, but by adding this line in both criteria, that leads the PA reviewer to look at both at the same time so there doesn't leave room for error.	Dr. Foster moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.
2. Blanket Statement – New Indications/Age Changes	**Background:** This revision modifies all prior authorization criteria to include a statement regarding new and/or non-listed indications or age for use changes. This revision expands coverage for indications or age that are not addressed in current prior authorization criteria. In addition, the Provider Group identifier would change to Billing Code Type. No other changes will be made. **Public Comment:** None.	.

TOPIC	DISCUSSION	DECISION
B. Revised Prior Authorization (PA) Criteria 2. Blanket Statement – New Indications/Age Changes (Continued)	**Board Discussion:** There was concern about unintended consequences, but the State clarified that the blanket statement is not a part of the PA criteria itself. The blanket statement applies for when there is a request for an indication or an age that's not listed on the PA, pertaining to those drugs listed on the PA. The package insert will be the PA reviewer's reference for approval criteria. The DUR Board meets quarterly, but additional indications and age group approvals from the FDA happen much more frequently. This is something that has been an issue, that was needing to be addressed. This is the solution the state is proposing.	Dr. Foster moved to approve. Dr. Stutzman seconded the motion. The motion was approved unanimously.
	At 10:38 a.m., it was moved and seconded that a brief recess be taken for meeting attendees to move their vehicles out of the tow zones. The meeting was called back to order at 10:46 a.m.	
3. CGRP Receptor Antagonists	**Background:** The prior authorization criteria were last revised in January 2019 and is being revised to clarify the criteria for use. **Public Comment:** None. **Board Discussion:** The Board inquired if the purpose for this update was ensuring one treatment is used appropriately and adequately before initiating a second treatment. The State responded that when talking to PA reviewers, a doctor will say a patient failed Botox® but then they are now wanting to go back to Botox®. This is ensuring that there is a proper length of treatment with a drug before saying it has failed.	Dr. Backes moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.
4. Botulinum Toxins	**Background:** The prior authorization criteria were last revised in January 2019 and is being revised to clarify the criteria for use. **Public Comment:** None.	

TOPIC	DISCUSSION	DECISION
B. Revised Prior Authorization (PA) Criteria 4. Botulinum Toxins (Continued)	**Board Discussion:** A Board member cited an example of a patient being on Botox® and not receiving the response they want, then they try something else and that doesn't give them the relief that Botox® did, will this change prevent them from being able to go back to Botox®? The State responded that this will allow the patient to go back to Botox®, but not until the next scheduled dose of the previous drug. A Board member commented that most of these medications have multiple indications and asked if that is the reason why the State did not create a migraine disease state PA. The State replied that it wasn't ready to address Botox®'s numerous indications, at this time.	Dr. Backes moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.
5. Topiramate Extended Release	**Background:** The prior authorization criteria were last revised in April 2019 and is being revised to clarify the criteria for use. **Public Comment:** None. **Board Discussion:** None.	Dr. Foster moved to approve. Ms. Stutzman seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION
C. New Prior Authorization (PA) Criteria 1. Adult Rheumatoid Arthritis	**Background:** These criteria will combine and supersede all previous criteria for agents used for the treatment of adult rheumatoid arthritis. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. **Public Comment:** Laura Hill with AbbVie brought to the State's attention under General Criteria for Initial PA, the CDAI score should reflect moderate disease activity and that Humira® can be given 40mg SQ weekly. Phil King with Pfizer asked for clarification concerning a patient who has an adverse reaction/not having an appropriate response in the 90 days, if that patient would then go to the conventional DMARD requirement or would they have to go to one of the products in table 1 and would that be considered a trial and failure if they were not able to complete the full 90 days of methotrexate therapy. The State answered that the contraindication would allow them to bypass that, but any other separate bullet criteria they would still have to meet. Mr. King asked the State when they consider disease activity to begin. The State responded that the provider would have to determine that. He also asked for clarification regarding an example of a patient being on therapy and having control but then losing control in that year window, coming back and no longer meeting the renewal criteria, what mechanism is in place, so they don't have to go back through the methotrexate trial again. The State responded that the look-back window was removed, and the dates of original therapy is all that is needed.	

TOPIC	DISCUSSION	DECISION
C. New Prior Authorization (PA) Criteria 1. Adult Rheumatoid Arthritis (Continued)	**Board Discussion:** Amendments to the criteria were made to address the CDAI score and the weekly dosing of Humira®.	Dr. Clair moved to approve as amended. Dr. Foster seconded the motion. The motion was approved unanimously.
2. Ankylosing Spondylitis	**Background:** These criteria will combine and supersede all previous criteria for agents used for the treatment of ankylosing spondylitis. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. **Public Comment:** None. **Board Discussion** None.	Ms. Stutzman moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.
3. Asthma	**Background:** These criteria will combine and supersede all previous criteria for agents used for the treatment of asthma. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. **Public Comment:** Kevin Duhrlops from Sanofi had a question on "90 days out of the last 120 days". This was misstated unintentionally and was amended to say "at least 90 consecutive days". There was discussion regarding prerequisite treatments that most likely would have been tried. The State replied that those should be on the medical record and could be listed on the PA form to use for PA approval. **Board Discussion:** The Board agreed to the change.	Dr. Backes moved to approve as amended. Dr. Foster seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION
C. New Prior Authorization (PA) Criteria 4. Atopic Dermatitis	**Background:** These criteria will combine and supersede all previous criteria for agents used for the treatment of atopic dermatitis. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. **Public Comment:** Kevin Duhrkopf with Sanofi Genzyme brought to the Board's attention that dupilumab has recently added a new indication for chronic rhinosinusitis. Mr. Duhrkopf also spoke to the Board about his concerns of clinicians thinking they need to go to a TCI or topical corticosteroid before a biologic when the patient is already beyond those agents and the factors clinicians use to determine whether it's mild to moderate or moderate to severe and if it could be clarified better. The State answered that if the patient is at the moderate or severe state when they're requesting this drug, they would have already used those agents when they were in the mild or moderate state, so they would have already met those mile markers and should be able to document it. **Board Discussion:** A Board member asked Mr. Duhrlops if the EASI score is not clinically friendly and if there are guidelines or an independent reference that can be utilized. Mr. Duhrlops replied that there are guidelines and it is usually step therapy, but the tools used in clinical trials have not been validated in clinical practice.	Ms. Stutzman moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.

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C. New Prior Authorization (PA) Criteria 5. Crohn's Disease	**Background:** These criteria will combine and supersede all previous criteria for agents used for the treatment of Crohn's disease. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. **Public Comment:** Laura Hill with AbbVie pointed out a typographical error, which was amended. **Board Discussion:** None.	Dr. Foster moved to approve as amended. Dr. Clair seconded the motion. The motion was approved unanimously.
6. Juvenile Idiopathic Arthritis	**Background:** These criteria will combine and supersede all previous criteria for agents used for the treatment of juvenile idiopathic arthritis. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents. **Public Comment:** None. **Board Discussion:** None.	Dr. Backes moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION
C. New Prior Authorization (PA) Criteria 7. Plaque Psoriasis	**Background:** These criteria will combine and supersede all previous criteria for agents used for the treatment of plaque psoriasis. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. **Public Comment:** Laura Hill with AbbVie spoke to the Board about the current criteria meeting a definition of severe plaque psoriasis with a BSA of at least 10% involvement or involvement of a sensitive body part. Current recommendations by American Academy of Dermatology and National Psoriasis Foundation state it's appropriate to consider use of biologics in moderate to severe plaque psoriasis. Moderate psoriasis is defined by a BSA 3-10%. Ms. Hill suggested the Board consider lowering the threshold. She stated that in the past, the National Psoriasis Foundation has put out a consensus paper suggesting a threshold of 5%. **Board Discussion:** The Board asked Ms. Hill if there are any other guidelines that suggest differently. Ms. Hill replied that the American Academy of Dermatology's old recommendation threshold of 10% was fairly common and the newest guidelines do not state an exact threshold. They state that biologics are appropriate in patients that have moderate to severe disease and define moderate as 3-10% BSA, severe as 10% or above, and given that these drugs are approved for moderate to severe use, the current criteria are restricting to only severe plaque psoriasis. The Board asked Ms. Hill if there is a table for what biologic is specifically approved by the FDA. Ms. Hill answered that all the agents are approved for moderate to severe. The State and Board agreed to lower the BSA threshold to 3% to reflect a moderate to severe disease state.	Dr. Backes moved to approve as amended. Dr. Snow seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION
C. New Prior Authorization (PA) Criteria 8. Psoriatic Arthritis	**Background:** These criteria will combine and supersede all previous criteria for agents used for the treatment of psoriatic arthritis. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. **Public Comment:** Phil King with Pfizer spoke to the Board about Bullet 3 under General Criteria for Initial PA and pointed out ACR guidelines recommend a TNF inhibitor over methotrexate. Mr. King also commented that these patients present with a number of different symptoms and it may not be swollen and tender joints and he encouraged the Board to look at some other reported patient outcomes or possibly incorporating some of the plaque psoriasis criteria. The State replied that in the Guidelines they recommend TNF inhibitors before methotrexate, and it had low or very low level of evidence. It was noted that the Guidelines did refer to the European Guidelines which were published in 2015 when they considered whether they should recommend TNF inhibitors over methotrexate but ultimately decided to go with methotrexate. Mr. King also spoke about the PsA populations and whether there are other good measures included as a marker treatment target. The State responded that in looking at most recent guidelines, EASI scale is used for these studies and guidelines did mention it's cumbersome to use in clinical practice and it is rarely used, that is why it wasn't included. The other thing considered was BSA because psoriatic arthritis is a combination of plaque psoriasis and then you get arthritis later, but in looking through package inserts, nobody reported BSA so it couldn't be included. Laura Hill with AbbVie spoke about the joint and skin component of psoriatic arthritis and clarified that there is no minimum number of swollen/tender joint involvement.	

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C. New Prior Authorization (PA) Criteria 8. Psoriatic Arthritis (Continued)	**Board Discussion:** The Board asked what was considered the definition of low evidence. The State answered low evidence is low quality of evidence in the types of studies that were done. Amendments were made to the initial and renewal response measures for tender and swollen joints disease state status.	Ms. Stutzman moved to approve as amended. Dr. Rice seconded the motion. The motion was approved unanimously.
9. Ulcerative Colitis	**Background:** These criteria will combine and supersede all previous criteria for agents used for the treatment of ulcerative colitis. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. **Public Comment:** Phil King with Pfizer asked the State for clarification on whether this was for the moderate to severe patient. He also noted that as part of this criteria, it should be specified that this is for patients who have moderate to severe ulcerative colitis and these recommendations would change for a mild to moderate patient. The State inquired of Mr. King if he felt the thresholds that are listed are consistent with moderate to severe, to which he responded yes. The Board questioned Mr. King whether he felt additional verbiage is needed to state moderate to severe. Mr. King responded that based on some of the other bullet point criteria, it would be beneficial. Mr. King recommended the State reconsider adding "could be used in combination with" but to have it as an absolute 90-day monotherapy window only might not be consistent. The State replied that its intention was to have the 90 days for the thiopurine, not for the corticosteroids, because once you reach remission, you might be less than 90 days when you're on a corticosteroid. Mr. King commented that it addresses the contraindication, but it doesn't address the ability to do dual therapy in these patients through the induction process and encouraged the State to update its references. There are 14 listed and there's only 12 in the references and most of those are the package insert references and that their product does not list a specific time course for steroid exposure and nothing concerning thiopurine.	

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C. New Prior Authorization (PA) Criteria 9. Ulcerative Colitis (Continued)	**Board Discussion:** The State commented that the intention is not to keep a patient on a steroid, it is once they get to remission, the provider can decide when the patient can taper off of it. The Board questioned whether the only thing this would do would require 90 days of monotherapy trial with steroid before this medication can be added on. The State replied not from the steroid but from azathioprine. Mr. King encouraged the Board to review the Guidelines, as he doesn't feel they are being interpreted on the same level. The Board asked if this is an 'and/or' statement, you either do it for 90 days or you've reached remission. The State responded it doesn't talk about how long it takes to get to remission. The Board commented that if you have a patient that presents, and you want to induce remission, you can use multiple agents, that later on in the disease they're going to be exposed to multiple medications, so the PA criteria would be less of an issue at that point so this should be the area of focus. MCOs commented that rather than focusing on the induction the focus should be on the maintenance regimen because people who qualify for biologics are the ones who become steroid-dependent and asked if there is anything in the guidelines to shift the focus to the type of people who should benefit from biologics. Bullet point 3 was removed under General Criteria for Initial PA and will be further researched and brought back in October.	Dr. Backes moved to approve with changes. Dr. Snow seconded the motion. The motion was approved unanimously, on the condition that it will be brought back to the October DUR meeting.
10. Spinal Muscular Atrophy	**Background:** These criteria will combine and supersede all previous criteria for agents used for the treatment of spinal muscular atrophy. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. **Public Comment:** Brian Howell with Avexis brought to the Board's attention that Zolgensma's® label is not only for type 1 patients. He also commented that it is indicated for 2 years and younger. The State clarified with him whether you have to have symptoms prior to 6 months of age. Mr. Howell responded you don't have to have symptoms, the data in the clinical trials	

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C. New Prior Authorization (PA) Criteria 10. Spinal Muscular Atrophy (Continued)	only noted that it was that particular group of patients that was primarily dosed. The State commented that "symptoms prior to 6 months of age" will remain since that is what the clinical studies have. Biran Patel with Biogen spoke to the Board about the last bullet of Initial Approval for Spinraza® where it states, "Patient is not on permanent ventilation" and distinguished for the Board between population types in the clinical trials. He asked what a physician would do if they wanted to put a ventilated patient on Spinraza®. The State replied that commercial insurance has the non-ventilation use requirement. Mr. Howell asked for a clarification on infantile and later onset patients in the bullet point. The State answered that that is only for the infant population, it's not addressing the adult population, but they are not opposed to being more specific. Mr. Patel reminded the Board that Spinraza® is not contraindicated based on the label. The State inquired if a type 2 or 3 SMA patient is permanently ventilated, what's the benefit from Spinraza®; do they recover from that? Mr. Patel responded that in terms of reversibility, they see more stabilization and keep them where they're at in terms of their function and see that more often in older patients. When it comes to infants, you can see improvement the earlier you dose, however, for adult patients, you want to see stabilization, and noted positive data and trials on this, however, specific ventilated patient groups weren't looked at. The State commented that there isn't enough evidence to support removing that criteria. **<u>Board Discussion:</u>** The Board asked what the SMA count was in Kansas. The State replied their current data showed 5 patients.	Ms. Stutzman moved to approve as amended. Dr. Clair seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION
D. Mental Health Medication Advisory Committee (MHMAC) 1. Antidepressants – Safe Use for All Ages	**Background:** At the May 2019 MHMAC meeting, the committee revised the criteria for use of Antidepressants – Safe Use for All Ages prior authorization (PA), to include Spravato®. The criteria were last reviewed in October 2018. **Public Comment:** Erin Hohman with Janssen yielded her time back to the Board with the offer to answer any questions they may have concerning Spravato®. **Board Discussion:** The Chairman of the Board reminded everyone that all the recommendations that come from the MHMAC have to be approved in total and cannot be amended by this Board. A Board member questioned bullet 4, "Prescriber has addressed the appropriateness of psychotherapy with the patient" and asked for clarification on the reasoning for that. The State responded that the drug also has addictive potential. MCOs also responded that the Committee was wanting to make sure psychotherapy was addressed with the patient. The State confirmed it will be an attestation by the prescriber. A Board member was unclear whether they were approving Spravato®. The State clarified that if the Board agrees with the PA Criteria as it stands, then it is approved, but they must accept or deny in whole. The State also mentioned to the Board that this PA will be brought back to the August MHMAC meeting for possible amendments but would like it to be approved as is here, so it could be effective in 60 days.	Dr. Foster moved to approve. Dr. Clair seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION
E. Miscellaneous Items 1. Managed Care Organization Annual Reports	**Background:** Aetna Better Health of Kansas, Sunflower State Health Plan, and UnitedHealthcare Community Plan presented reports detailing utilization trends and provider education efforts for 2018. i. Aetna Individual Report – Alan Carter, PharmD ii. Sunflower Individual Report – Angie Zhou, PharmD iii. UnitedHealthcare Individual Report – Jeanne Cavanaugh, PharmD **Public Comment:** None. **Board Discussion:** None.	
IV. Appointment of Chairperson and Interim Chairperson	A motion and a second was made for Dr. Mittal to continue as the DUR Board Chairperson. A vote was taken and passed unanimously. A motion and a second was made for Dr. Backes to continue as the DUR Interim Chairperson. A vote was taken and passed unanimously.	Ms. Stutzman moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously. Dr. Foster moved to approve. Ms. Stutzman seconded the motion. The motion was approved unanimously.
V. Open Public Comment	None.	
VI. Adjourn	The meeting adjourned at 1:07 p.m.	Dr. Backes moved to adjourn. Dr. Rice seconded the motion. The motion to adjourn was approved unanimously.

The next DUR Board meeting is scheduled for October 9, 2019.

All approved PA criteria are posted to the KDHE website- http://www.kdheks.gov/hcf/pharmacy/pa criteria.htm